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IN THE
Supreme Court of the United States
OCTOBER TERM, 1994

BARR LABORATORIES, INC.,
Petitioner,

v.

BURROUGHS WELLCOME CO.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITIONER'S REPLY MEMORANDUM

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A would-be inventor, Ms. *A*, believes that a particular compound may cure a terrible disease. She thinks that the idea has a one in ten million chance of working (or for that matter, thinks her idea will *not* work). Having a few hours of time on her hands (and living in a first-to-file jurisdiction such as the United Kingdom), she prepares a draft patent application that includes a boilerplate enumeration of all known dosage forms and routes of administration, a dosage frequency of "four or more" per day, and an extraordinarily broad range of "suitable" dosage sizes. Ms. *A* puts the draft application aside and does not then file it.

Dr. *B* is a scientist who is "uniquely qualified" in the field (i.e., not merely the proverbial "pair of hands").

Aware of Dr. *B*'s qualifications, Ms. *A* mentions her idea to Dr. *B* and asks him to see whether it will work. Dr. *B* employs a unique process that he has patented and discovers that the compound in fact will cure the disease. A month after Dr. *B* gives Ms. *A* the happy results of his experiments, Ms. *A* files her patent application, still composed mostly of boilerplate text. Under the decision of the court of appeals in this case, and notwithstanding the patent code's provision for joint inventorship, 35 U.S.C. § 256, Ms. *A* is the *sole* inventor and Dr. *B* has *no* rights in the invention or the resulting patent. Pet. App. 9a, 15a.

Petitioner Barr Laboratories, Inc. (Barr) seeks review of this remarkable proposition. The issue is important to the field of pharmaceutical patents, and the court of appeals' decision allows mere speculation or hope to create patent rights that exclude from coinventorship individuals whose contributions are essential to the conception of the patentable item or process.

Respondents Burroughs Wellcome Co. (BW) does not dispute Barr's characterization of the court of appeals' decision. BW instead contends that the ruling is and should be the law. Respondent's Brief in Opposition (Opposition Brief) at 5-6. BW claims that other, unrelated aspects of the patent code will prevent the mere listing of a compound from constituting conception. *Id.* at 14.

> In the pharmaceutical field, a complete conception often requires that the inventor be able to describe the structure of the drug and how to make it along with such details as effective dosages, routes of administration, dosage forms, frequency of dosing and the like.

Id.

Does this supposed set of limitations protect against premature and unwarranted awards of patent rights? Apparently not. The court of appeals upheld as sufficient

to establish conception a draft patent application setting forth remarkably broad, open-ended ranges.

BW assures us that the pharmaceutical inventor must provide "such details as . . . routes of administration." *Id.* Let us examine the "details" of the route of administration that the court of appeals has said are sufficiently focused to constitute conception:

> The formulations include those suitable for *oral, rectal, nasal, topical (including buccal and sublingual, vaginal or parenteral (including subcutaneous, intramuscular, intravenous and intradermal)* administration.

A. 5323 (emphasis added).[1]

For "details" of dosage forms, the BW application offers the reader brief generic sketches of how to make capsules, tablets, liquids, lozenges, pastilles, mouthwashes, suppositories, snuff-type powder, nasal spray or drops, tampons, gels, creams, foams, and sterile injectable solutions. A. 5323-24.

As for the "details" of effective dosages, the application states that "a suitable effective dose will be in the range *1.0 to 250 mg* per kilogram body weight of recipient per day, preferably in the range of 1 to 100 mg per kilogram body weight per day and most preferably in the range 5 to 40 mg per kilogram body weight per day." A. 5322 (emphasis added).

When frequency of dosing is considered, we are told that "[t]he desired dose is preferably presented as two, three, *four or more* sub-doses" per day, "in unit dosage forms, for example, containing *5 to 500 mg*, preferably 10 to 200 mg and most preferably 20 to 100 mg of active ingredient per unit dosage form." *Id.* (emphasis added). For a patient weighing 150 pounds these boilerplate numbers yield a dosage of between 140 mg and *70,000 mg or more* per day.[2]

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[1] References to "A. ——" are to the Record on Appeal.

[2] 70,000 mg is equal to 154 pounds.

If a requirement for setting forth these kinds of "details" is what protects against unduly free awards of patent rights, BW has done more to make the case for review than anything Barr could say. BW's draft application occupied the entire field of potential "details" by listing virtually every known route of administration and dosage form, a dosage frequency of between two and an infinite number per day, and a "suitable effective" dosage weight ranging from 1 mg all the way up to 250 mg, yet the draft BW application met the test prescribed by the court of appeals.[3]

BW erects and knocks down various other straw issues that are irrelevant to the question presented by the petition. For example, BW claims that Barr would apply a "reasonable expectation" test to all instances of conception of an invention. Opposition Brief at 12. Barr's contention, of course, is that this test applies only in such complex and unpredictable fields as pharmaceutical chemistry and biology—fields where only with suitable experimentation can one have any reliable idea whether a particular compound will work in a particular manner. BW does not even cite, let alone distinguish, one of the principal decisions cited by Barr in support of Barr's position. *Biel v. Chessin*, 347 F.2d 898, 146 U.S.P.Q. 293 (C.C.P.A. 1965), written by no less a patent authority than Judge Giles Rich, teaches that where the invention is "a method of treating the human body . . . , conception thereof is a far different thing than merely thinking of the use of the compound. *There must be some concomitant reasonable understanding or appreciation of the fact that the compound would work* and in what way." *Biel*, 347 F.2d at 902-03, 146 U.S.P.Q. at 296-97 (emphasis added); *see also Amgen, Inc. v. Chugai*

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[3] Additionally, of course, BW's draft patent application was withheld from filing until the NIH tested the drug against the human retrovirus HIV in a human cell system, thereby establishing that AZT actually works. Pet. App. 4a-5a. Only then did BW file its application. *Id.* 5a.

Pharmaceutical Co., Ltd., 927 F.2d 1200, 1207, 18 U.S.P.Q.2d 1016, 1021 (Fed. Cir. 1989) (more than "mere speculation" required) (conception of compound incomplete without ability to define compound), *cert. denied*, 502 U.S. 856 (1991).

BW says that an inventor need not "understand the scientific basis for the invention in order to obtain a patent." Opposition Brief at 13 (citing *Diamond Rubber Co. v. Consolidated Rubber Tire Co.*, 220 U.S. 428, 435-36 (1911)). The issue here, of course, is not whether BW understood how the invention would work but whether one can be an inventor when one has no belief or reason to believe (or even disbelieves) that the idea will work.

BW also offers the unremarkable proposition that where nothing more than routine skill is required to demonstrate the utility of a drug, the individual exercising such skill is not the inventor. *Id.* (citing *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1387, 181 U.S.P.Q. 453, 457-58 (C.C.P.A. 1974)). Here, of course, the court of appeals took pains to point out that the contribution of Dr. Broder and his colleagues at NIH was at a level far exceeding routine skill. Pet. App. at 14a-15a. "Broder and Mitsuya, and very few others, were uniquely qualified" to perform the experiments and interpret the results. *Id.*

BW makes much of a decision addressing a proposition not at issue here. Opposition Brief at 13 (citing *MacMillan v. Moffett*, 432 F.2d 1237, 167 U.S.P.Q. 550 (C.C.P.A. 1970)). *MacMillan* rejected the proposition that one must *know* an idea will work in order to be the inventor. *Id.*, 432 F.2d at 1240, 167 U.S.P.Q. at 553. Requiring actual, positive knowledge (as *MacMillan* declined to do) is one thing. Requiring that a would-be inventor have *some* basis for believing an idea will work, or at least requiring that the individual not *disbelieve* that the idea will work, as is the case here, is quite another.

MacMillan is inapposite for another reason. MacMillan was held not to be a coinventor because he "was merely conducting standard tests." *Id.* Here the court of appeals found that testing and evaluation conducted by NIH was anything but "standard." Pet. App. 14a-15a.

None of these straw issues is relevant. The court of appeals found itself at the juncture of two conflicting lines of authority. One line suggests that conception requires only that a would-be inventor state his idea with particularity. *E.g., Mergenthaler v. Scudder,* 11 App. D.C. 264, 1897 C.D. 724 (D.C. Cir. 1897). This line allows little more than speculation to constitute conception, but the issue typically does not arise in fields where existing knowledge itself affords a reasonable expectation whether an invention will work. The second line of decisions recognizes that in complex, unpredictable fields like pharmaceutical chemistry and physiology, "merely thinking of the use of [a] compound" is insufficient to constitute conception. *Biel v. Chessin,* 347 F.2d at 902-03, 146 U.S.P.Q. at 296-97; *accord Smith v. Bosquet,* 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940).

In attempting to resolve these conflicting lines of authority, the court of appeals has all but wiped out the latter line. In so doing the court has set the threshold for what constitutes conception so low that mere hope or expectation, *Alpert v. Slatin,* 305 F.2d 891, 894 (C.C.P.A. 1962), or mere speculation, *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.,* 927 F.2d at 1207, 18 U.S.P.Q.2d at 1021, instead of some reason to believe that an idea will work, henceforth will be sufficient to secure sole inventorship of lucrative pharmaceutical patents. This does violence to the intent of the patent code and should not be permitted.

CONCLUSION

For the reasons set forth in the petition and above, the petition for certiorari should be granted.

Respectfully submitted,

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